Nos. 89-1391, 89-1392

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

DR. IRVING RUST, on behalf of himself, his patients, and all others similarly situated, DR. MELVIN PADAWER, on behalf of himself, his patients, and all others similarly situated, MEDICAL AND HEALTH RESEARCH ASSOCIATION OF NEW YORK CITY, INC., PLANNED PARENTHOOD OF NEW YORK CITY, INC., PLANNED PARENTHOOD OF WESTCHESTER/ ROCKLAND, and HEALTH SERVICES OF HUDSON COUNTY, NEW JERSEY,

Petitioners,

—v.—

DR. LOUIS SULLIVAN, or his successor, Secretary of the United States Department of Health and Human Services,

Respondent.

THE STATE OF NEW YORK, THE CITY OF NEW YORK, THE NEW YORK CITY HEALTH & HOSPITALS CORP.,

Petitioners,

—v.—

DR. LOUIS SULLIVAN, or his successor, Secretary of the United States Department of Health and Human Services,

Respondent.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF *AMICI CURIAE* THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE AMERICAN COLLEGE OF PHYSICIANS, *ET AL.*, IN SUPPORT OF PETITIONERS

(*Amici continued on inside cover*)

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INTEREST OF *AMICI CURIAE*

Amicus the American Public Health Association ("APHA") is a national organization devoted to the promotion and protection of personal and environmental health and to disease prevention. Founded in 1872, APHA is the largest public health organization in the world with over 50,000 members. It represents all disciplines and specialties in public health, including patients and health professionals such as physicians, nurses, health educators and family planning specialists.

The other *amici* on whose behalf this brief is submitted[1] include associations of health care professionals, all of whom are dedicated to the advancement of public health in the United States, experienced in the study of public health problems and committed to finding solutions to pressing public health concerns. Their membership consists of thousands of women and men throughout the country, many of whom are engaged in the delivery of reproductive health care and work in Title X-funded facilities. Other *amici*, including the United States Conference of Mayors, are committed to the implementation of sound public health policy.

At issue in this case are new Title X regulations which, if upheld, will have devastating consequences for public health care and for poor women. In a number of ways discussed below, they are a blueprint for substandard medical care and a threat to the health and lives of those Title X was intended to serve. Because the regulations run counter to fundamental public health principles in which *amici* firmly believe and which they strive to promote, *amici* urge this Court to strike them down.

While *amici* believe that the regulations violate the constitutional rights of women and health care providers, they confine themselves in this brief to demonstrating that the reg-

1 *Amici* have the consent of the parties to file this brief and letters of consent have been filed separately in this Court.

ulations contravene the congressional purpose of providing medical care for poor women and safeguarding their reproductive health.

SUMMARY OF ARGUMENT

Almost two decades ago, Congress enacted Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.* (1982 & Supp. 1990) ("Title X" or the "Act") — a milestone in the advancement of public health in this country. As Congress intended, Title X has brought family planning services to millions of low-income women who, prior to passage of the Act, lacked access to a family planning program of any kind. As Congress envisioned, Title X has fostered the creation of programs offering a broad range of family planning services as well as general medical care ancillary to those services. These programs also serve as valuable sources of referral to other health care providers. Thus, Title X has established a vital point of entry for poor women into the general health care system and has brought continuity of care to a system marred by fragmentation.

Title X provides that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." § 1008, 42 U.S.C. § 300a-6. Notwithstanding the national debate over abortion, the government has, until now, interpreted this provision to permit, and since 1981 to require, that Title X programs provide nondirective abortion counseling and referrals. Only funding for abortion procedures was considered barred.[2]

2 *See* Special Subcommittee on Human Resources, Senate Committee on Labor and Public Welfare, 92d Cong., 1st Sess., *Report of the Secretary of Health, Education and Welfare Submitting Five-Year Plan for Family Planning Services and Population Research Program* 318 (Comm. Print 1971); *see also* 36 Fed. Reg. 18,465 (1971), *revised by* 45 Fed. Reg. 37,437 (1980) (codified at 42 C.F.R. § 59.5(b)(2) (1986)); United States Department of Health and Human Services, *Program Guidelines for Project Grants for Family Planning Services* § 8.6 (1981) (Title X grantees must provide pregnant clients with nondirective counseling on and referral upon request for "[p]renatal care and delivery[;] [i]nfant care, foster care, or adoption[; and] [p]regnancy termination.")

On February 2, 1988, in a sharp break with this longstanding interpretation, the Secretary of the United States Department of Health and Human Services (the "Secretary" or "HHS") promulgated new regulations under the Act which ban all abortion counseling, even if conducted in a nondirective manner, and all referral for abortion. § 59.8(a)(1).[3] The pregnant woman with a serious or potentially life-threatening disease can no longer be told that her pregnancy poses substantial health risks that may require an abortion to protect her health. The pregnant woman at high risk of delivering a child with a severe or fatal birth defect can no longer make an informed choice whether to carry her pregnancy to term. Instead, once the Title X patient is diagnosed as pregnant, she "must" be referred for prenatal care "by furnishing a list of available providers that promote the welfare of mother and unborn child." § 59.8(a)(2).

The regulations' prohibition of all abortion counseling and referral is relentless in scope. If a pregnant woman asks her doctor for information about abortion or where she can get an abortion, her questions must not be answered. Even if a pregnant woman with a fatal disease, such as AIDS, asks whether an abortion will prolong her life, no responsive answer will be forthcoming. Instead, the regulations direct the Title X physician to advise that "the project does not consider abortion an appropriate method of family planning and therefore does not counsel or refer for abortion." § 59.8(a)(5).

If the pregnant woman seeks an abortion on her own, her ability to find an appropriate provider is severely restricted. The regulations require that the referral list exclude providers

3 *See* 53 Fed. Reg. 2944-46 (1988) (codified at 42 C.F.R. §§ 59.2, 59.5, 59.7, 59.8, 59.9 and 59.10). Hereinafter, reference to these regulations will be by section number ("§ _____").

whose "principal business is the provision of abortions." § 59.8(a)(3). This limitation effectively excludes virtually all abortion providers the Title X patient has access to or can afford. It will also cause hazardous delay in obtaining an abortion.

The only exception to mandatory referral for prenatal care is when "emergency care" is required. § 59.8(a)(2). Although "emergency" is not defined, the regulations' one example (ectopic pregnancy) makes clear that only health conditions which are imminently life-threatening will justify a referral for abortion. § 59.8(b)(2). For the many pregnant women who are not at immediate risk, but who suffer from a condition which may be worsened or rendered life-threatening if pregnancy is carried to term, such as severe diabetes, cancer or heart disease, this exception is of no help.

The regulations further demand that Title X-funded clinics be both physically and financially separate from programs engaging in "prohibited" activities. § 59.9. This onerous requirement, which runs counter to all notions of continuity of care, will cause many Title X programs to curtail their services or close altogether.

While Congress hardly intended to harm the beneficiaries of the health care program it created, the regulations at issue do precisely that. They deprive poor women of information necessary to make vital health care decisions. In mandating only one kind of referral, they disregard the individual's medical needs, and steer women on a course which risks jeopardizing their health, and at times, their lives.

The damage caused to the physician-patient relationship is equally destructive. To ensure that adequate care is afforded the patient, the dialogue between doctor and patient must be open and honest. The script the regulations require the Title X physician to follow is anything but honest. It forces the health care professional to obfuscate answers to life and death questions. Attempts to place words in the mouth of the physician have been rejected by this Court. *See Thornburgh v. American College of Obstetricians & Gynecologists*, 476

U.S. 747 (1986); *City of Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416 (1983). Any deviation from this precedent will result in the provision of substandard health care to those women most in need — the very antithesis of what Title X was designed to achieve.

Despite the national tensions over abortion, the Title X program has functioned effectively for the past twenty years. By prohibiting funding for abortion while permitting nondirective option-counseling, Congress achieved a careful balance which ensured delivery of services in conformity with professional standards of care and integration of family planning services into general health care programs. The regulations seek to destroy that balance and, if upheld, will reverse two decades of progress in public health care for poor women.

ARGUMENT

I. THE REGULATIONS SUBVERT THE PURPOSES FOR WHICH TITLE X WAS ENACTED AND CONTRAVENE SOUND PUBLIC HEALTH POLICY BY ENDANGERING THE HEALTH OF THE VERY WOMEN THEY PURPORT TO SERVE

When Title X was enacted in 1970, it was estimated that 5 million indigent women in the United States were in need of family planning services and more than 60% of the nation's counties lacked an identifiable family planning program of any kind.[4] To remedy this "extreme" health care shortage,[5] Congress enacted Title X which requires that "priority . . . be given . . . to the furnishing of [family planning] services to persons from low-income families . . . ." 42 U.S.C. § 300a-4(c)(1).

Title X is now the single largest source of federal funding for family planning services, funding 3900 clinics and serving

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4 *See* S. Rep. No. 1004, 91st Cong., 2d Sess. 9 (1970).

5 *Id.*

nearly 4.5 million people each year. *See* Morley ¶ 6 (224 JA).[6] In 1986, in New York State alone, Title X-funded agencies served nearly 240,000 women, at least 70,000 of whom were adolescents. *See* Gesche ¶¶ 6-7 (171 JA); Fink ¶¶ 3, 7 (160-61 JA). Title X programs provide family planning services to the most vulnerable women in our society. Approximately 90% of these women have incomes below 150% of the poverty line and over 30% are teenagers. *See Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d 53, 56 (1st Cir. 1990) (*en banc*), *petition for cert. filed*, 58 U.S.L.W. 3819 (U.S. June 26, 1990) (No. 89-1929); Gesche ¶ 7 (171 JA). For many of them, the Title X-funded clinic is their only source of health care — they do not have and cannot afford private doctors. *See* Drisgula ¶¶ 18-19 (153-54 JA); Tiezzi ¶ 8(a) (272-73 JA); Merrens ¶ 5 (284 JA).

Congress further intended that Title X programs serve as a point of entry into the general health care system for millions of low-income women. This was to be accomplished in two ways. First, in requiring that Title X programs "offer a broad range of acceptable and effective family planning methods and services" (42 U.S.C. § 300(a)), Congress intended that such programs provide "much more than the dispensation of contraceptive devices."[7] Second, Congress intended that family planning services be integrated into — not separated from — general health care programs.[8]

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6 Citation to the materials in the parties' Joint Appendix filed in this Court are accompanied by a reference to the page number as ("_____ JA"). Citation to the materials in the parties' Joint Appendix filed in the Second Circuit are accompanied by a reference to the page number as ("_____ A"). All references to affidavits and declarations in the record will be to the last name, paragraph number and appendix page.

7 S. Rep. No. 1004, 91st Cong., 2d Sess. 10 (1970).

8 *See* H.R. Rep. No. 1472, 91st Cong., 2d Sess. 7, *reprinted in* 1970 U.S. Code Cong. & Admin. News 5068, 5074; H.R. Conf. Rep. No. 1524, 93d Cong., 2d Sess. 58 (1974); S. Rep. No. 29, 94th Cong., 1st Sess. 66, *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 528; *see also Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d at 59.

Thus, HHS' first Five Year Plan for the Title X program, submitted to Congress pursuant to 42 U.S.C. § 300a-6a, stated:

> In addition to specific contraceptive services, programs should make available other related medical examinations and tests to assist in the early detection of illness and disease. While the program cannot provide full medical care because of its specialized nature, services should be provided for the screening and referral, including followup, of the patient to appropriate physicians, hospitals or other programs for necessary treatment. *This mechanism is vital, given the fact that family planning is often the point of entry into a fragmented health care system for many individuals.*[9]

In 1975, when Congress reauthorized Title X, the Senate Committee Report accompanying reauthorization cited with approval the broad scope of medical and social services provided by Title X programs,[10] and emphasized that, whenever possible, these services should be "integrat[ed] into all programs offering general health care."[11]

The congressional mandate to assess the general health of the patient enabled the Title X provider to uncover illness and disease and, if the patient was pregnant, to counsel her about the impact of pregnancy on her health. The congressional mandate to integrate Title X services into general health

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9 Special Subcommittee on Human Resources, Senate Committee on Labor and Public Welfare, 92d Cong., 1st Sess., *Report of the Secretary of Health, Education and Welfare Submitting Five-Year Plan for Family Planning Services and Population Research Program* 318 (Comm. Print 1971) (emphasis added) (41 JA).

10 These medical services include "general medical examinations, pelvic and breast examinations, pap smears and other diagnostic laboratory tests, as well as the provision of infertility services and contraceptives." S. Rep. No. 29, 94th Cong., 1st Sess. 55, *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 517.

11 S. Rep. No. 29, 94th Cong., 1st Sess. 66, *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 528.

care programs facilitated, if not ensured, appropriate referral of the patient to other providers for specialized treatment. Over the past two decades, Title X providers have achieved considerable success in complying with these two mandates.

Congress also contemplated that Title X programs would deliver services in accordance with legal and ethical standards of care,[12] as embodied in informed consent statutes throughout the nation, judicially developed common law and canons of medical ethics. Title X providers have always adhered to these standards and, until promulgation of these regulations, nothing has prevented them from doing so.

As demonstrated below, the regulations do not comport with the purposes underlying Title X — they betray them. They exceed the Secretary's rule-making power and must be struck down. *See United States v. Larionoff*, 431 U.S. 864, 873 n.12 (1977).

A. The Regulations' Ban On Abortion Counseling And Referral Seriously Jeopardizes The Health Of Women Served By Title X Programs

Disregarding the careful balance struck by Congress in prohibiting funding of abortion while permitting abortion counseling, the regulations radically alter what information a Title X provider may give to its patients. Section 59.8(a)(1) provides:

> A Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning.

The effect of this prohibition is to block women's access to information necessary to protect their health and, at times, their lives.

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12 *See* H.R. Rep. No. 1161, 93d Cong., 2d Sess. 18-19 (1974); H.R. Conf. Rep. No. 1524, 93d Cong., 2d Sess. 57 (1974); S. Rep. No. 29, 94th Cong., 1st Sess. 62, *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 524-25; *see also* 121 Cong. Rec. 9781 (1975).

Consider the pregnant woman who suffers from:

- **AIDS** (Acquired Immune Deficiency Syndrome) — AIDS is the number one cause of death in New York City among women aged 25 to 34, the prime child bearing years when women most often use family planning clinics.[13] Joseph ¶ 7 (199 JA). "Viral disease theory suggests that pregnancy may accelerate the progression of HIV disease, AIDS and AIDS-related complex." Minkoff ¶ 7 (647A) (citation omitted); *see also* Morley ¶ 17 (228-29 JA);

- **acquired or congenital heart disease** — often cited as the most common non-obstetrical cause of maternal mortality. Rosenfield ¶ 10 (681A);

- **hypertension** — associated with up to 30% of maternal deaths and up to 22% of perinatal deaths. *Id.*, ¶ 11 (683A);

- **diabetes** — pregnant diabetics experience an increased risk of diabetic or insulin coma, leg edema, pre-eclampsia and infection. *Id.*, ¶ 12 (683A); *see* Rust ¶ 17(a) (254-55 JA);

- **sickle cell anemia** — pregnancy results in more frequent and severe crises, infections such as pneumonia, increasingly severe anemia, congestive heart failure and pulmonary complications such as embolus. Rosenfield ¶ 14 (684A); or

- **a malignant breast tumor that is estrogen receptor positive** — in which case pregnancy may accelerate the spread of cancer. *Id.*, ¶ 15.

Appropriate medical practice dictates that the Title X physician inform the pregnant woman who suffers from these (or other) potentially life-threatening diseases of the implications of such a diagnosis on her health, and on the fetus she is car-

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13 "Title X-funded clinics are . . . likely to serve a disproportionately high number of HIV positive pregnant women." Minkoff ¶ 6 (647A); *see* Joseph ¶ 8 (199 JA).

rying, and that pregnancy may accelerate the progression of the disease. The regulations, however, contemplate a far different scenario — one which conceals from these unfortunate women the dire consequences of carrying their pregnancy to term.

Because all abortion counseling is forbidden, the Title X physician is barred from informing the patient that her pregnancy poses serious health risks that may require an abortion to preserve her health and prolong her life. Even if the pregnant woman with AIDS, or cancer, or heart disease asks: "Doctor, can you give me some information about abortion?" or "Doctor, will an abortion prolong my life?" or "Doctor, where can I go for an abortion?" the Title X physician may only reply:

> [This] project does not consider abortion an appropriate method of family planning and therefore does not counsel or refer for abortion. . . . [This] project can help [you] to obtain prenatal care and necessary social services, and provide [you] with a list of such providers from which [you] may choose.

§ 59.8(b)(5).

The counseling ban will also deny many women the option of making an informed choice not to carry and deliver a child with a severe or fatal birth defect. According to Dr. James H. Sammons, Executive Vice President of the American Medical Association:

> [C]ertain maternal disorders greatly increase perinatal mortality and morbidity and may require discussion of pregnancy termination as an option pursuant to providing full disclosure of medical information. For example, congenital abnormalities occur two to three times more often among children of diabetic women, and the abnormalities associated with prenatal diabetes are more severe and more often multiple and fatal. Similarly, a pregnant woman may be infected with a disease such as

> AIDS, rubella, herpes, cytomegalovirus or toxoplasmosis, that could have devastating effects on her fetus.
>
> In addition, some pregnant women may be at high risk of delivering a child with a severe genetic disorder. This group includes women of advanced maternal age (over 35) who are at an increased risk of having a child with a chromosomal abnormality such as Down's Syndrome; . . . women who previously had a child with a genetic disorder such as polycystic kidney disease; and women who have a history of multifactorial disorders such as anencephaly in their families.

Sammons ¶¶ 10, 11 (264-65 JA) (citations and footnote omitted).

The doctor's forced silence about the health risks posed by pregnancy and his canned response to questions about abortion may very well mislead the Title X patient into believing that her pregnancy will not accelerate the course of her disease or give her the mistaken impression that abortion is unsafe and illegal. *See* Merrens ¶¶ 15, 17 (284-86 JA); Drisgula ¶ 20 (154 JA).[14] Even for patients who are not so misled, the regulations' referral provisions impose severe obstacles to obtaining vital information and treatment.

Once pregnancy has been diagnosed, the regulations compel the Title X physician to refer the pregnant patient:

> for appropriate prenatal and/or social services *by furnishing a list of available providers that promote the welfare of mother and unborn child.* She must also be provided with information necessary to protect the health of mother and unborn child until such time as the referral appointment is kept.

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14 *See Planned Parenthood Ass'n Chicago Area v. Kempiners*, 568 F. Supp. 1490, 1497 (N.D. Ill. 1983) (*on remand*) ("It is blinking at reality to say that a woman's counselor, who of necessity occupies a position of great trust and intimacy, discusses only childbirth and refuses to provide any information on abortion, will not have a critical impact upon the woman's decision whether to carry her pregnancy to term.")

§ 59.8(a)(2) (emphasis added). By prohibiting all discussion of abortion and limiting referrals only to health care providers "that promote the welfare of mother and unborn child," the medical needs of the individual patient are totally ignored. *See* Cohen ¶ 4 (509A); Tiezzi ¶ 8(c) (274 JA). Absent an immediate life-threatening emergency (*see* Point IB), the patient is affirmatively steered toward carrying her pregnancy to term even though an abortion may be medically warranted in the interests of her health. *See* Morley ¶ 17 (228-29 JA); Rust ¶ 17(a) (254-55 JA); Sammons ¶ 7 (263 JA); Rosenfield ¶¶ 5, 7 (679A-680A); Cohen ¶ 6 (510A).

The regulations further restrict a woman's access to responsible and complete option-counseling by forbidding a Title X project from using:

> prenatal, social service or emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning . . . *by including on the list of referral[s] . . . health care providers whose principal business is the provision of abortions* . . . .

§ 59.8(a)(3) (emphasis added).[15]

By excluding from the referral list providers whose "principal business" is providing abortions, the Secretary is effectively excluding virtually all abortion providers Title X patients have access to or can afford. *See* Henshaw ¶¶ 12, 21 (192, 195-96 JA); Gordon ¶ 3 (180 JA). Seventy percent of all abortions nationwide are performed at clinics which would likely be included within the "principal business" definition. *See* Henshaw ¶ 12 (192 JA). Allowed to remain on the list would be hospitals and private practitioners. However, most Title X patients cannot afford private physicians, for these providers generally do not accept Medicaid or charge fees on

15 Moreover, even if the patient asks which providers on the list perform abortions, the physician would be acting at his own risk to tell her. Section 59.8(a)(3) of the regulations forbids the use of referrals "as an indirect means of encouraging or promoting abortion . . . by 'steering' clients to providers who offer abortion . . . ."

a sliding scale basis, and few Title X patients carry any type of health insurance. *See* Drisgula ¶ 28 (156 JA); Gordon ¶¶ 3, 6-11 (180-83 JA); Henshaw ¶ 12 (192 JA); Pasternack ¶ 14(d) (673A-674A). Hospital costs for abortions also are prohibitive for most Title X patients. *See* Drisgula ¶ 28 (156 JA); Gordon ¶¶ 3, 6-9 (180-83 JA); Henshaw ¶ 12 (192 JA). Finally, many communities simply have no other public providers of abortion services. Randolph ¶¶ 10, 12, 14 (244-45 JA); Coombs ¶ 11 (144-45 JA); Merrens ¶ 5 (284 JA).

The Secretary attempts to disguise the harsh impact of the regulations by claiming that the pregnant woman who is diagnosed with a serious health condition can be "referred to the appropriate specialist for treatment of the condition." 53 Fed. Reg. 2932. Presumably, the specialist can counsel about abortion, assuming he is not a recipient of Title X funds. However, if the woman is not told that her pregnancy may jeopardize her health or endanger her life, she will not understand the need for immediate treatment. By the time she visits the specialist and is finally informed of her options, it may be too late or too dangerous to have an abortion, especially if the specialist has to refer her to yet another health care provider that performs abortions. *See* Gesche ¶ 16 (174-75 JA); Henshaw ¶¶ 15, 21 (193, 195-96 JA); Morley ¶ 12 (227 JA).

Delays in obtaining abortion will undoubtedly subject women to increased health risks.[16] The mortality risk for abortion increases 50% with each week after the eighth week of pregnancy, while the risk of major complications (morbid-

16 In invalidating the regulations as an undue burden on the right recognized in *Roe v. Wade*, 410 U.S. 113 (1973), the First Circuit stated:

> the regulations impose substantial delay and additional costs upon a woman desiring to terminate her pregnancy. Some low-income women may be unable to obtain any information on abortion at all without the help of [the] Title X clinic. For others, the delay between the moment when they learn of their pregnancy and the time they obtain information on abortion may greatly increase the risks inherent in the abortion procedure.

Massachusetts v. Secretary of Health & Human Servs., 899 F.2d at 67 (footnote omitted).

ity) increases about 30% each week after the eighth week. *See* Morley ¶¶ 12-13 (227 JA); *see also* Sammons ¶ 12 (266 JA); Cohen ¶ 3 (509A). Moreover, many women seeking abortions are unfamiliar with the procedure and the increased health risk associated with obtaining an abortion after the first trimester. Under the regulations, however, Title X providers are barred from telling their patients of this health risk and from encouraging them not to delay in deciding whether to have an abortion. *See* Merrens ¶ 16 (285 JA).

In sum, far from ensuring that low-income women receive adequate information and treatment to protect their health, the regulations' referral provisions foster exactly the opposite result. Lacking adequate information and counseling, some Title X patients will attempt carrying their pregnancy to term, blind to the fact that pregnancy may worsen a pre-existing condition and seriously endanger their health or life, with potentially devastating effects on the fetus. Others will carry unwanted pregnancies to term, either because of delays in finding a provider who can perform an affordable abortion or the inability to find an abortion provider altogether. Still others will obtain abortions from unlicensed providers at great physical risk or attempt dangerous self-abortions. *See* Rust ¶¶ 11, 14-15 (252-54 JA).

B. The Deleterious Impact Of The Regulations Is Not Lessened By The Vague Emergency Exception

The so-called emergency exception set forth in section 59.8(a)(2) of the regulations affords little solace to pregnant women suffering from serious health conditions which are aggravated or rendered life-threatening by pregnancy. Section 59.8(a)(2) provides:

> [in] cases in which emergency care is required . . . the Title X project shall be required only to refer the client immediately to an appropriate provider of emergency medical services.

By declining to define "emergency" except by reference to ectopic pregnancy (*see* 59.8(b)(2)),[17] the Secretary clearly indicates that an "emergency" is defined by the need for *immediate* surgery, and does not extend to conditions such as AIDS, cancer, hypertension, kidney disease and heart disease, all of which may be life-threatening to the mother and the fetus, although not necessarily requiring immediate action upon diagnosis. *See* Rosenfield ¶¶ 9, 21-22 (680A-681A; 687A-689A); Rust ¶ 17(a) (254-55 JA).

Even assuming the Secretary intended a broader reading of the exception, without any definition of "emergency," Title X providers are afforded no guidance as to which emergency referrals would be sanctioned under the regulations and which would not. Instead, the regulations leave it to bureaucrats to decide, on a case-by-case basis and after the fact, whether a particular condition met the Secretary's amorphous view of "emergency." Title X providers are left at risk of cessation of funding if a judgment is made with which the Secretary later disagrees.

The limited and obscure nature of the emergency exception emphasizes the extremely narrow authorization for referrals under the regulations, a narrowness that can endanger the life of the mother and fetus as well.

C. The Regulations Force Title X Practitioners To Conduct Themselves In A Manner Violative Of Legal And Ethical Standards Of Care, And Destroy The Integrity Of The Physician-Patient Relationship

In dictating what Title X physicians can say to their patients and what they cannot, the regulations violate the

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17 An ectopic pregnancy occurs when the fertilized ovum implants itself elsewhere than in the uterine cavity. It is the leading cause of death during the first trimester. Immediate surgery is necessary to curb potentially catastrophic events such as ruptured tubal pregnancy and massive hemorrhaging. *See* F. Cunningham, P. MacDonald & N. Gant, *Williams Obstetrics* (18th ed. 1989) 511-532; Centers for Disease Control, *CDC Surveillance Summaries* (September 1989), *MMWR* (Vol. 38, No. SS-2 1989) 1.

essence of informed consent and, as a result, destroy the integrity of the physician-patient relationship. All health care professionals would agree that "[w]ithholding of information concerning the progression of a fatal disease is unconscionable." Minkoff ¶ 8 (648A); *see also* Sammons ¶¶ 8, 9 (263-64 JA). Yet, in prohibiting the Title X provider from advising the pregnant woman that an abortion will prolong or save her life, the regulations compel such "unconscionable" results.

1. The Regulations Violate Principles Of Informed Consent As Embodied In State Statutes, Decisional Law And Canons Of Medical Ethics

A "root premise" of American jurisprudence is that "[e]very human being . . . has a right to determine what shall be done with his own body. . . ." *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972) (quoting *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 105 N.E. 92, 93 (1914)). The patient is able to exercise her right to make her own decisions about medical treatment only if the physician fully and accurately discloses all information necessary to permit her to make an informed choice. *Id.* at 780. This duty may further oblige the physician to advise the patient to consider one alternative over another depending on the circumstances. *Id.* at 781.

As this Court recently stated, "[t]he informed consent doctrine has become firmly entrenched in American tort law." *Cruzan v. Director, Missouri Dep't of Health*, 58 U.S.L.W. 4916, 4918 (U.S. June 25, 1990). The doctrine has been affirmatively recognized by common law[18] or by statute in

18 *See, e.g.*, cases collected in 69 A.L.R.3d 1250 (1988) ("Malpractice: Physician's Duty to Inform Patient of Nature and Hazards of Treatment in Pregnancy and Childbirth Cases Under the Doctrine of Informed Consent").

virtually every American jurisdiction.[19] In New York, for example, doctors are under a legal duty to provide a pregnant woman with "sufficient information concerning her condition and alternatives so that she [can] reasonably decide whether she [is] willing to undergo the entire pregnancy and deliver the child or abort the pregnancy . . . ." *Becker v. Schwartz*, 60 A.D.2d 587, 400 N.Y.S.2d 119, 119-120 (2d Dep't 1977) (citation omitted), *modified on other grounds*, 46 N.Y.2d 401 (1978).

Similarly, the New York Public Health Law requires a physician to "disclose [treatment] alternatives . . . and the reasonably foreseeable risks and benefits involved as a reasonable . . . practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation." N.Y. Public Health Law § 2805(d)(1) (McKinney Supp. 1990).

Canons of medical ethics are virtually uniform in their requirement of informed consent. It is fundamental that the physician present "the medical facts accurately to the patient . . . and make recommendations for management in accordance with good medical practice." *Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association* ¶ 8.07 (1986) (hereinafter "*Current AMA Opinions*") (80-81 JA).

The physician also has an "ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice." *Current AMA Opinions* ¶ 8.07 (81 JA); *see* Sammons ¶ 13 (266-67 JA); Rosenfield ¶¶ 5, 7 (679A-680A); Comment Letter of the APHA (Oct. 30, 1987) ¶ 3 (183A-184A). In so doing, the "physician is obliged to mention all alternative treatments, including those he or she does not provide or favor, so long as they are

19 *See* 3 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* (1982) Appendix L (hereinafter "President's Commission").

supported by respectable medical opinion." President's Commission at 76; see Katz ¶ 11 (208-209 JA).

Thus, "[i]n the event of an unwanted pregnancy, the physician should counsel the patient about her options of continuing the pregnancy to term and keeping the infant . . . [or] offering the infant for legal adoption, or aborting the pregnancy." American College of Obstetricians and Gynecologists ("ACOG"), *Standards for Obstetric-Gynecologic Services* at 57 (6th ed. 1985) (78 JA); *see* Morley ¶¶ 18-19 (229-30 JA); Comment Letter of ACOG (Nov. 2, 1987) at 4-6 (192A-194A). The physician is also ethically bound to "refer a patient for diagnostic or therapeutic services to another physician . . . or any other provider of health care services permitted by law to furnish such services, whenever he believes that this may benefit the patient." *Current AMA Opinions* ¶ 3.04 (80 JA).

By prohibiting all abortion counseling and slanting the referrals list in favor of health care providers that "promote the welfare of mother and unborn child," the regulations mandate that Title X physicians leave their patients singularly uninformed or misinformed about the risks associated with their pregnancy. Such deliberate manipulation of the physician-patient dialogue not only forces doctors to violate fundamental legal and ethical standards of care but will also expose Title X providers to malpractice suits, professional censure and loss of their licenses. *See* Morley ¶¶ 21-22 (230-31 JA); Katz ¶ 6 (207 JA).

The Secretary argues, however, that the ban on counseling and referral cannot result in the violation of informed consent by any Title X physician, because state laws impose informed consent obligations only on the doctor who will be treating the patient. Since the Title X program is barred from providing treatment related to pregnancy (or for other conditions unrelated to family planning), "it has no need to obtain consent to such treatment." 53 Fed. Reg. 2932.

In raising this specious argument, the Secretary diverts attention from the fact that the regulations compel Title X

providers to affirmatively mislead their patients. This, in and of itself, is unethical and illegal. In any event, the Secretary's argument is patently incorrect.

Case law in no way supports the suggestion that health care professionals, who diagnose a dangerous condition which they will not ultimately treat, do not have any informed consent obligations with respect to counseling and referral for treatment. In *Canterbury v. Spence*, the court held that the physician's duty to disclose goes far beyond mere diagnosis:

> A physician is under a duty to treat his patient skillfully but proficiency in diagnosis and therapy is not the full measure of his responsibility. The cases demonstrate that the physician is under an obligation to communicate specific information to the patient when the exigencies of reasonable care call for it. Due care may require a physician perceiving symptoms of bodily abnormality to alert the patient to the condition. It may call upon the physician confronting an ailment which does not respond to his ministrations to inform the patient thereof. It may command the physician to instruct the patient as to any limitations to be presently observed for his own welfare, and as to any precautionary therapy he should seek in the future. It may oblige the physician to advise the patient of the need for or desirability of any alternative treatment promising greater benefit than that being pursued. Just as plainly, due care normally demands that the physician warn the patient of any risks to his well-being which contemplated therapy may involve.

464 F.2d at 781 (footnotes omitted); *see also Schroeder v. Perkel*, 87 N.J. 53, 432 A.2d 834, 839-40 (1981) (even though pediatricians would not themselves be providing pregnancy care or treatment, they could be liable for depriving the woman of information necessary to decide whether to risk bearing a child with a genetic disorder).

The Secretary's argument is also contrary to Title X's statutory design. As demonstrated above (*see* pp. 6-8), far from requiring that Title X projects be hermetically sealed off from a broader concern with, and integrated care of, a woman's health, Congress intended that Title X providers carry out their normal responsibility to inform a patient of medical risks she presently faces and possible courses of action, including treatment and outside referral. Indeed, a Title X provider may be, at any given time, the only health care professional with whom a patient has any ongoing relationship.

Thus, although "[a] physician may choose to limit his practice to certain diagnostic services, he may not neglect a patient under his care." *Current AMA Opinions* ¶ 3.05. *See* Cohen ¶ 5 (509A) ("[t]he physician's duty to counsel a pregnant patient about the medical aspects of her pregnancy arises as soon as the doctor-patient relationship is established"); *see also* Sammons ¶ 15 (267-68 JA).

2. The Regulations Violate Congressional Intent And Disregard Decisions Of This Court Reflecting Adherence To The Doctrine Of Informed Consent

A clear indication of congressional intent is required to uphold federal regulations, such as those at issue here, which have the effect of displacing state regulation in areas, such as health care, which are traditionally left to state control. *Bowen v. American Hosp. Ass'n*, 476 U.S. 610, 644-45 (1986) (regulations promulgated by HHS relating to health care for handicapped infants held statutorily unauthorized because they effectively displaced the traditional authority of the states to regulate health care decisions without clear indication of congressional intent to do so).[20]

20 *See also Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985) (noting the "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause[ ]"); *Head v. New Mexico Bd. of Examiners in Optometry*, 374 U.S. 424, 431-32 (1963); *cf. Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142, 144 (1963).

There is no evidence here that Congress, in enacting Title X, intended to preempt, override or in any way impair standards of acceptable medical practice or state informed consent law. Indeed, the legislative history demonstrates otherwise. The House Committee Report accompanying the 1974 reauthorization of Title X expressly stated that clients of Title X-funded clinics should receive "the basic elements of informed consent" including (i) "a description of any . . . risks reasonably to be expected . . ."; (ii) "a disclosure of any appropriate alternative methods or procedures that might be advantageous"; and (iii) "an offer to answer any inquiries concerning the procedures . . . ."[21] The Senate Committee Report accompanying the 1975 reauthorization of Title X reiterated that the principles of informed consent, including disclosure of medically appropriate alternatives, "must be applied with regard to the provision of any medical procedure or service" funded by Title X.[22]

Congressional intent is consistent with decisions of this Court which, while implicitly relying on the deeply embedded doctrine of informed consent, have repeatedly emphasized the "central role of the physician" in enabling a woman to exercise her right to reproductive choice. *Colautti v. Franklin*, 439 U.S. 379, 387 (1979); *see also Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 762-63 (1986); *City of Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416, 443-45 (1983); *Doe v. Bolton*, 410 U.S. 179, 192 (1973).

As was recognized in *City of Akron*, "because abortion is a medical procedure," the physician must be accorded " 'the room he needs to make his best medical judgment.' " 462 U.S. at 427 (quoting *Doe v. Bolton*, 410 U.S. 179, 192). "The physician's exercise of this medical judgment encompasses both assisting the woman in the decision-making pro-

21 H.R. Rep. No. 1161, 93d Cong., 2d Sess. 18-19 (1974).

22 S. Rep. No. 29, 94th Cong., 1st Sess. 62 (1975), *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 525; *see also* 121 Cong. Rec. 9781 (1975).

cess and implementing her decision should she choose abortion." *City of Akron*, 462 U.S. at 427. Thus, this Court has struck down provisions in abortion statutes which attempted to officially structure the physician-patient dialogue so as to manipulate the woman's choice between childbirth and abortion. *Id.* at 444-45; *Thornburgh*, 476 U.S. at 762-64.

Relying on this Court's decisions noted above, the First Circuit and the District of Colorado concluded that the regulations strip the physician of his ability to exercise his best medical judgment. *See Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d at 66-68; *Planned Parenthood Fed'n of America v. Bowen*, 680 F. Supp. 1465, *summary judgment granted*, 687 F. Supp. 540 (D. Col. 1988):

> The regulations impermissibly interfere with the central role of the physician by limiting his discretion and thereby imposing upon him an "undesired and uncomfortable straitjacket" which is constitutionally intolerable. [They] prohibit a physician from providing women with neutral and often medically appropriate information about abortion, and also prohibit abortion referrals.
>
> In addition . . . the regulations not only prohibit the physician from giving certain information, but actually require the physician to provide specific, censored information to [the pregnant woman], even if the information does not comport with the physician's view of the best interests of his patient. The Government's interest in regulating abortion "does not permit it to adopt regulations that depart from accepted medical practice." *Akron*, 462 U.S. at 431, 103 S.Ct. at 2493.

680 F. Supp. at 1474-75 (citations omitted).

II. THE REGULATIONS' SEPARATION REQUIREMENT WILL SIGNIFICANTLY REDUCE THE AVAILABILITY OF QUALITY HEALTH CARE FOR LOW-INCOME WOMEN AND SERIOUSLY IMPEDE CONTINUITY OF CARE

Section 59.9 of the regulations requires that Title X-funded clinics be both physically and financially separate from programs engaging in "prohibited activities," with compliance to be determined on a case-by-case basis using an array of factors wholly within HHS' discretion. The separation requirement does grave injustice to a fundamental principle of sound public health care — that "[p]rovision of comprehensive integrated services results in higher quality health care." Bennett ¶ 24 (502A).

All Title X clinics rely on state and federal funding (other than Title X) to provide a variety of reproductive health services (*i.e.*, family planning, abortion, prenatal, obstetric and postpartum services). *See, e.g.*, Drisgula ¶ 4 (149 JA); Fink ¶¶ 5, 7 (161 JA); Bennett ¶ 6 (496A); Felton ¶ 7 (526A). For example, many of these clinics provide prenatal and obstetric services with grants under the Maternal and Child Health Services ("MCH") Block Grant, Title V of the Social Security Act, 42 U.S.C. § 701. *See* Gesche ¶¶ 12, 22 (173, 177 JA); Drisgula ¶ 25 (155 JA). Since the regulations prohibit abortion counseling and referral, a Title X clinic would no longer be able to provide MCH Block prenatal services such as genetic counseling or amniocentesis, which may result in counseling involving the abortion option. *See* Gesche ¶ 22 (177 JA).

Section 59.9 wholly ignores the logical nexus between option-counseling, prenatal or pregnancy-termination services, obstetric care and infant care and, instead, forces poor women to seek this range of services at different sites. In the words of Dr. Irving Rust:

> Particularly where teens are involved, integrated services are needed to facilitate enrollment in counseling and family planning programs. Many of our patients first

> visit the clinic for pregnancy testing or abortion services although they may need counseling, family planning or prenatal care. Because of the proximity of services and personnel, we are able to immediately channel a patient into a program which meets her needs. For example, post abortion patients are immediately enrolled in the Bronx Center's family planning program on the same premises, where after counseling and discussion with a staff health professional, they select a contraceptive method. . . . Prompt and successful enrollment of patients in counseling, family planning and pre-natal programs would be impossible if the services were provided on different sites from abortion and abortion-related services.

Rust ¶ 18 (256 JA); *see* Bennett ¶ 14 (498A-499A).

The separation requirement not only destroys continuity of care, but will also force many Title X clinics to curtail services or close altogether. According to the American Public Health Association:

> The fiscal ramifications of these requirements are enormous[.] [E]ven state health departments, many of which have spent many years and dollars on carefully integrating their health programs to achieve greater efficiency and accountability, would be deeply affected and legitimate services cut.

Comment Letter of the APHA (Oct. 30, 1987), ¶ 6 (186A); *see* Bennett ¶ 23, 28 (501A-502A, 503A-504A); Gesche ¶ 18 (175-76 JA); Tiezzi ¶ 9 (275-76 JA).

In striking down the separation requirement, the First Circuit recognized what the Secretary chose to ignore: Section 59.9 runs counter to congressional intent underlying the abortion prohibition in Section 1008 of the statute and undermines Title X's central purposes in three distinct ways. *See Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d at 59-60.

First, the original Conference Report on Title X stated that the abortion prohibition in Section 1008 was "not intended to interfere with or limit programs" supported with other than Title X funds.[23] The effect of the separation requirement is to do precisely that.

Second, the Senate Committee Report accompanying the 1975 reauthorization of Title X encouraged the provision of Title X family planning services:

> not only in specialty clinics, but, where such facilities do not exist or are impractical, in entities devoted to comprehensive health care for low-income families.
>
> . . . [I]t is essential that there be close coordination and, whenever possible, integration of family planning services into all general health care programs.[24]

By contrast, the separation requirement mandates fragmentation, not integration, of services.

Third, the statute itself requires a state plan for a "*coordinated* and *comprehensive* program of family planning services" as a prerequisite to any Title X grant to a state health authority. 42 U.S.C. § 300a(a) (1982) (emphasis added). For all of these reasons, the First Circuit concluded that Section 59.9 would be "completely contrary to the express Congressional intention to expand family planning services" because its effect would be to limit those services. *Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d at 60.

If Section 59.9 is allowed to stand, Title X programs will no longer serve as an entry point into the general health care system for millions of low-income women. Instead, forced separation will cause a retreat to the days of fragmented public health care — fragmentation which Title X was intended to remedy and has gone far to overcome.

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23 H.R. Conf. Rep. No. 1667, 91st Cong., 2d Sess., *reprinted in* 1970 U.S. Code Cong. & Admin. News 5080, 5082.

24 S. Rep. No. 29, 94th Cong., 1st Sess. 66, *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 528.

CONCLUSION

For the foregoing reasons, the judgment below should be reversed and the regulations struck down.

Respectfully submitted,

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